



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
NATIONAL HEALTH & ENVIRONMENTAL EFFECTS RESEARCH LABORATORY
OFFICE OF RESEARCH AND DEVELOPMENT

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To Whom It May Concern:

Enclosed, please find Application for IRB Approval for the following study "An Epidemiologic Health Study of Manganese Exposure in Adult Residents of East Liverpool, Ohio." After discussions with Diane in your office, I would like to provide some context for this study. This is a U.S. Environmental Protection Agency Funded study to San Francisco State University (SFSU). The funded PI on the study is Dr. Rosemarie Bowler. We are submitting this protocol through the UNC IRB because our Human Subjects Review Official does have oversight on this project because the funding mechanism is contract. However, this study is an expansion of a previously completed study by Dr. Bowler's team which was funded as a grant and thus did not have direct oversight from our Human Subjects Review Official. Diane advised me to complete the application as the technical expert of the funder and include the already approved protocol from San Francisco State University IRB and to notify you that the Office for the Protection of Human Subjects at San Francisco State University will be the primary IRB of record for this field study.

Please note that a few of the documents have had small minor edits since the approval from SFSU. Dr. Bowler will submit amendments to SFSU's Office for the Protection of Human Subjects for all documents that have had edits after your review. These documents include: consent form, phone recruitment script, sample feedback letter and the study protocol. Please do not hesitate to contact me if you should have any questions.

Sincerely,

A handwritten signature in cursive script, reading "Danelle T. Lobdell", is positioned below the word "Sincerely,".

Danelle T. Lobdell, Ph.D.